

Application No. 10/632,658
Confirmation No. 3579
Atty. Docket No. GP103-03.DV1

Response to Notice of Non-Compliant Amendment
Art Unit: 1634
Examiner: Ethan C. Whisenant

IN THE CLAIMS:

Please amend claim 41, to correct dependency, as shown below.

1-36. (Canceled)

37. (Previously presented) A method of detecting HIV-1 nucleic acid in a biological sample, comprising the steps of:

providing a biological sample containing HIV-1 nucleic acid;

contacting the biological sample with at least one capture oligomer comprising a base sequence that hybridizes specifically to a target region in LTR or *pol* sequences of HIV-1 nucleic acid, thus forming a capture oligomer:HIV-1 nucleic acid complex;

separating the capture oligomer:HIV-1 nucleic acid complex from the biological sample;

amplifying *pol* sequences, or a cDNA made therefrom, by using at least two amplification oligomers selected from the group consisting of SEQ ID NO:10, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:42, SEQ ID NO:43, or SEQ ID NO:44 and a nucleic acid polymerase *in vitro* to produce an amplified product; and

detecting the amplified product using a labeled detection probe that hybridizes specifically with the amplified product, thereby indicating presence of the HIV-1 nucleic acid in the biological sample.

38. (Previously presented) The method of claim 37, wherein the contacting step uses a capture oligomer that hybridizes specifically to a target region in *pol* sequences of HIV-1 nucleic acid complementary to SEQ ID NO:3 or SEQ ID NO:5, or a combination of oligomers that hybridize specifically to target regions in *pol* sequences of HIV-1 nucleic acid complementary to SEQ ID NO:3 and SEQ ID NO:5.

39. (Previously presented) The method of claim 38, wherein the contacting step further

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comprises using a capture oligomer that hybridizes specifically to a target region in LTR sequences of HIV-1 nucleic acid.

40. (Previously presented) The method of claim 37, wherein the amplifying step uses at least two amplification oligomers, wherein a first amplification oligomer is a promoter primer having the sequence of SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:43, or SEQ ID NO:44, and a second amplification oligomer is a primer having the sequence of SEQ ID NO:10, SEQ ID NO:11, or SEQ ID NO:42.

41. (Currently amended) The method of claim ~~41~~ 40, wherein the amplifying step uses any of the following combinations of promoter-primers and primers:

promoter-primers consisting essentially of SEQ ID NO:13 and SEQ ID NO:15, with primers consisting essentially of SEQ ID NO:10 and SEQ ID NO:11;

promoter-primers consisting essentially of SEQ ID NO:13 and SEQ ID NO:15, with primers consisting essentially of SEQ ID NO:11 and SEQ ID NO:42; or

promoter-primers consisting essentially of SEQ ID NO:43 and SEQ ID NO:15, with primers consisting essentially of SEQ ID NO:10 and SEQ ID NO:11.

42. (Previously presented) The method of claim 37, wherein the amplifying step further uses at least two amplification oligomers that bind specifically to LTR sequences or to sequences complementary to LTR sequences.

43. (Previously presented) The method of claim 42, wherein the amplifying step uses at least two amplification oligomers for amplifying LTR sequences selected from the group consisting of: SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, SEQ ID NO:25, SEQ ID NO:26, SEQ ID NO:27, SEQ ID NO:28, SEQ ID NO:29, SEQ ID NO:30, SEQ ID NO:31, SEQ ID NO:32, SEQ ID NO:33, SEQ ID NO:34, SEQ ID NO:35, SEQ ID NO:36, SEQ ID NO:37, and SEQ ID NO:38.

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44. (Previously presented) The method of claim 37, wherein the detecting step uses at least one labeled detection probe having a *pol*-specific sequence consisting essentially of SEQ ID NO:17, SEQ ID NO:18, SEQ ID NO:46, SEQ ID NO:47, SEQ ID NO:48, SEQ ID NO:49, SEQ ID NO:50, SEQ ID NO:51, SEQ ID NO:52, SEQ ID NO:53, SEQ ID NO:54, SEQ ID NO:55, SEQ ID NO:56.

45. (Previously presented) The method of claim 37, wherein the detecting step uses a combination of at least two labeled detection probes made up of a first probe sequence that is about 22 to about 30 bases consisting essentially of SEQ ID NO:17, and a second probe sequence that is about 17 to about 20 bases consisting essentially of SEQ ID NO:18.

46. (Previously presented) The method of claim 37, wherein the detecting step uses a combination of at least two labeled detection probes made up of at least one probe that has a *pol*-specific sequence of about 22 to about 30 bases consisting essentially of SEQ ID NO:17 or about 17 to about 20 bases consisting essentially of SEQ ID NO:18, and at least one probe that has a LTR-specific sequence.

47. (Previously presented) The method of claim 37, wherein the detecting step uses at least one labeled detection probe that includes at least one 2'-methoxy backbone linkage.

48. (Previously presented) A kit comprising a combination of oligomers, wherein oligomers contained in the kit have sequences consisting essentially of SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:13, and SEQ ID NO:15.

49. (Previously presented) The kit of claim 48, further comprising oligomers having base sequences consisting essentially of SEQ ID NO:17 and SEQ ID NO:18.

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50. (Previously presented) A composition comprising a combination of at least two oligomers selected from the group consisting of:

SEQ ID NO:12, optionally with a promoter sequence covalently attached to the 5' end of SEQ ID NO:12;

SEQ ID NO:14, optionally with a promoter sequence covalently attached to the 5' end of SEQ ID NO:14;

SEQ ID NO:10;

SEQ ID NO:11; and

SEQ ID NO:42.

51. (Previously presented) The composition of claim 50, wherein the promoter sequence is a T7 RNA polymerase promoter sequence.

52. (Previously presented) The composition of claim 50, wherein the composition further comprises an oligomer of SEQ ID NO:17, SEQ ID NO:18, or a mixture of oligomers of SEQ ID NO:17 and SEQ ID NO:18.

53. (Previously presented) The composition of claim 50, wherein an oligomer base sequence is linked by a backbone that includes at least one 2'-methoxy RNA group, at least one 2' fluoro-substituted RNA group, at least one peptide nucleic acid linkage, at least one phosphorothioate linkage, at least one methylphosphonate linkage or any combination thereof.

54. (Previously presented) The composition of claim 50, wherein an oligomer base sequence is linked by a backbone that includes at least one 2'-methoxy RNA group, at least one 2' fluoro-substituted RNA group, at least one peptide nucleic acid linkage, at least one phosphorothioate linkage, at least one methylphosphonate linkage or any combination thereof.

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55. (Previously presented) The composition of claim 52, wherein the oligomer comprises at least one 2'-methoxy RNA group in the backbone.

56. (Previously presented) The composition of claim 52, wherein the oligomer is linked to a detectable label.